

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As correctly indicated by the Office Action, claims 1-22 are currently pending. Claim 3 has been amended herein to remove "preferably is 0.5-100 μm " and "most preferably 1-25 μm ". This language has been made the subject of new claims 23-24, which depend on claim 3.

As these new claims recite language which was present in the claims and specification as-filed, Applicants submit that no new matter is presented by way of the present Amendment. Applicants reserve the right to file a divisional or continuation application based on any subject matter deleted by way of the present Amendment.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph, because the term "preferably" is purportedly indefinite.

For purposes of clarification, claim 3 has been amended herein to remove "preferably is 0.5-100 μm " and "most preferably 1-25 μm ". This language has been made the subject of new claims 23-24, which depend on claim 3. Thus, Applicants submit that this rejection is obviated.

Rejections under 35 U.S.C. § 102(b)

Claims 1-2, 4, 7-9, 11-16 and 20-21 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Oshlack *et al.* (U.S. Patent No. 5,639,476).

For proving anticipation, "anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." Jamesbury Corp. v. Litton Industrial Products, Inc. 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). The cited reference does not describe or suggest all of the elements of the rejected claims, as discussed in greater detail below.

The claims of the present invention are based on the concept of using solid water soluble pore-formers in water based coating dispersion to coat pharmaceutical preparations, such as tablets and pellets. In order for the present invention to be effective, it is necessary to use a pore-former with balanced water solubility, as recited in part (b) of claim 1. Thus, the solubility must be low enough (less than 50mg/ml in water) such that it can be suspended in water, without dissolving, but also high enough (more than 1 mg/ml in body fluid) to be dissolved from the finish product in the gastrointestinal tract.

In contrast, Oshlack *et al.* disclose that pore-formers can be used with polymers for coatings. The pore formers can be solid, liquid or dissolved and the fluid can be water or organic solvent. Oshlack *et al.* disclose many pore-formers and groups of pore-formers. However, Applicants note that these pore-formers cannot be suspended in water to form a suspension, because they are too soluble in water (for example, methocel E5, potassium chloride and sucrose). Instead, Oshlack *et al.* teach the skilled artisan that these pore-formers can be used together with organic solvents, suspended in the organic solvent, or

dissolved in water. Oshlack *et al.* gives a broad description of coatings, both organic and water based, but does not treat them separately when teaching of the pore-formers.

Thus, Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. 103(a)

Claims 1-22 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Oshlack *et al.*

To make a *prima facie* case of obviousness, the Federal Circuit has articulated the analysis of a proper analysis under 35 U.S.C. § 103 as follows:

[W]here claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). It respectfully is submitted that a legally sufficient *prima facie* case of obviousness has not been adduced, because the art cited by the Examiner, alone or in combination, does not suggest the claimed methods, let alone that the claimed methods could be conducted with a reasonable expectation of success.

None of the many pore-formers disclosed in Oshlack *et al.* can be used as pore-former in the present invention. Oshlack *et al.* only teach and suggest examples with water soluble pore-formers, which cannot be used with the presently claimed invention. For example, methocel E5 is a highly water-soluble polymer, and is far more soluble than the 100mg/ml recited by the present invention. Triethyl citrate is a liquid and used as a plasticiser. Aquacoat is the water dispersion of the water insoluble polymer. No other compounds are used in the coating in the examples of Oshlack *et al.* Further, the broad disclosure of Oshlack *et al.* of pharmaceutical coatings does not teach in anyway how the present invention could be made. Nor does it give the slightest indication that the present invention is even possible.

In addition, Applicants submit that the present invention produces surprising and unexpected results of , and thus, it would not have been obvious to optimize the teachings of the prior art to arrive at the claimed invention.

Prior to Applicants' invention, the methods of the prior art suffered from the problem of how to include a solid water soluble pore-former in an aqueous dispersion of the membrane polymer. There was the general notion in the art that this goal was impossible. Most, if not all, knowledgeable in the field that were told about the idea, stated that it could not be done. Now that it exists, many in the art tend not to believe it is true. Thus, the present invention has not been described before, nor is it an obvious solution. The present invention has resulted in a way to achieve a coating with the certain properties, while exchanging the organic solvent polymer solution with aqueous polymer dispersion. Water-soluble pore-formers could not be used, because they dissolve and give a coating with different properties. The concept unexpectedly discovered in the present invention was the balanced solubility solid pore-former. The present invention is based on the

discovery that not only must the pore-former dissolve in the gastrointestinal tract during any possible circumstance, but also dissolve sufficiently fast. Consequently equilibrium aqueous solubility must neither be too high or low and the particle-size distribution must be sufficiently low. The pore-former must be suspendable in water without forming aggregates, such as lumps, while retaining the correct particle-size. Furthermore, the tendency to form lumps increases both with increasing water solubility and decreasing particle-size. Also, particles suspended in water will grow in size since there is a migration of mass from small to larger particles.

The development of the claimed invention unexpectedly avoids problems such as aggregation, dissolution rate, incompatibility with the polymer dispersion, particle growth, particle size, unstable coating dispersion, and clogging of the spray nozzle. During manufacturing, the concentration of pore-former in the dispersion is high, about 100mg/ml. A finished large (1 g) tablet will contain about 100mg pore-former that dissolves in 1 litre of water within an hour. Thus, the claimed invention provides "a greater than expected result" which is evidence of nonobviousness.

It is well established in the art that the presence of an unexpected, advantageous or superior result is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963). Along these lines, it is also well established that "a greater than expected result" is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Corkill*, 711 F.2d 1496, 226 U.S.P.Q. 1005 (Fed. Cir. 1985).

Finally, the Office Action states that although Oshlack *et al.* do not specifically teach the claimed particle size of the pore formers of the present invention, the determination of particle size is within the scope of the skilled artisan. Applicants respectfully submit that although particle size is important to the characterization of the present invention, it is not an element which renders great patentable weight to the claims.

Therefore, since Applicants' claimed invention achieves surprising and unexpected results not present in the prior art references and even previously considered in the art to be impossible to achieve, and in light of the above remarks, Applicants respectfully request the withdrawal of this rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Attachment to Amendment and Reply

Marked-up Claim 3

3. (Twice Amended) A method according to claim 1, wherein the mean particle size of the pore-forming agent is 0.1-500 μm [, preferably is 0.5-100 μm and the most preferably 1-25 μm].